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APPENDIX B

510(k) PREMARKET NOTIFICATION SUMMARY
(per 21 CFR 807.92)

ICL 15 HFPL System
ICL 60 PLUS HFPL System (Models 40, 100 and 250)
ICL 100 ACTIVO Scanner System (Models P3 and P6)

I. Applicant:

USA Laser Biotech Inc.
10115 Merrimac Road
Richmond, VA 23235
Telephone: 804/320-4616

Key Contact: Nelson Marquina, PhD

II. Device Name

Proprietary Name:
ICL 15 HFPL System
ICL 60 PLUS HFPL System (Models 40, 100 and 250)
ICL 100 ACTIVO Scanner System (Models P3 and P6)

Common / Usual Name:	Infrared Lamp
Classification Name:	Infrared Lamp (21 CFR 890.5500)
Product Code:	ILY

III. Intended Use of the Device

The ICL IR Heat Lamp Systems are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local blood circulation and/or promoting relaxation of muscle.

IV. Predicate Devices

The ICL IR Heat Lamp Systems are substantially equivalent to other infrared therapeutic lamps that are currently in commercial distribution. These predicate devices include the Light Force Therapy, Inc. Super Nova and Acubeam Systems (K001179) and the Meditech International Inc BioFlex Professional Therapy System (K023621).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2004

USA Laser Biotech Inc.
C/o Ms. M. Joyce Heinrich
Texas Applied Biomedical Services, Inc.
12101 Cullen Boulevard, #A
Houston Texas, 77047

Re: K042256
Trade/Device Name: ICL 15 HFPL System
ICL 60 Plus HFPL System (Models 40, 100, and 250)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: August 18, 2004
Received: August 24, 2004

Dear Ms. Heinrich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT I

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Indications for Use

510(k) Number (if known): K042256

Device Name:

ICL 15 HFPL System
ICL 60 Plus HFPL System (Models 40, 100 and 250)

Indications for Use:

The ICL IR Heat Lamp Systems, as listed above, are intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm; the temporary increase in local blood circulation; and / or the temporary relaxation of muscle.

Prescription Use: X **AND/OR Over the Counter Use:** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODpE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042256

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